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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,132	07/23/2001	Rainer Mueller	RDID0073US	2393

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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 12/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/911,132	MUELLER ET AL.
	Examiner Maria B Marvich, PhD	Art Unit 1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 6 and 7 is/are allowed.

6) Claim(s) 1-5 and 8-13 is/are rejected.

7) Claim(s) 14 and 15 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 07 February 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: *attachment on Biological Deposits*

**DETAILED ACTION**

Claims 1-15 are pending in this application.

***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, a product of nature.

***Claim Objections***

Claim 15 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim 14 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9 and 10 and by dependency 2-5 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague in that applicants recite uses of various vectors or cells but do not recite how these elements are to be used. For example, applicants recite “a first vector is utilized” but do not definitively indicate how it is utilized; applicants recite “transformants are used” and “a second vector is used” but do not indicate how they are used

Use of the phrase “low concentration of a first selection marker” and “increased selection pressure” in claim 1 is broad and indefinite. The terms “low” and “increased” are relative ones not defined by the claim, no single set of conditions is recognized by the art as defining “low” or “increased” and because the specification does not provide a standard for ascertaining the

requisite degree, the metes and bounds of this claim cannot be established and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 1 recites the limitation "the gene copy" in claim 1. There is insufficient antecedent basis for this limitation in the claim and since there are two different genes recited in the claims, it is unclear what gene copy is being referred to in the claim.

Claim 9 recites the limitation "the expression cassette" in claim 9. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the specific transformation vectors, pHAP10-3 and pHAP10-3/9K, are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The invention does not recite use of any vector but instead specifically claims pHAP10-3 and pHAP10-3/9K. Applicants note that the pHAP10 and pHAP10-3/9K vectors use the commercially available Invitrogen vectors pPICZ $\alpha$ A and pPic9k vectors into which applicants insert the inventive gene under control of the AOX1 promoter. However, commercial availability is not necessarily evidence that the public will have access to

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the material for the life of a patent (see MPEP 2404.01). pHAP10-3 and pHAP10-3/9K availability in an unrestricted form for the life of a patent issued on the instant application cannot be ensured. Applicants must therefore themselves deposit pHAP10-3 and pHAP10-3/9K recited in the claims and thus satisfy the deposit requirement under 37 CFR 1.801-1.809 (see enclosed Suggestion for deposit of biological material).

Claims 1-5 and 8-13 are rejected.

Claims 14 and 15 are objected.

Claims 6 and 7 are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

December 20, 2002

DAVID GUZO  
PRIMARY EXAMINER  
